

PATENT COOPERATION TREATY FILE COPY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference CE-003PCT	FOR FURTHER ACTION		See Form PCT/IPEA/416																								
International application No. PCT/US04/34618	International filing date (day/month/year) 20 October 2004 (20.10.2004)	Priority date (day/month/year) 20 October 2003 (20.10.2003)																									
International Patent Classification (IPC) or national classification and IPC IPC: Please See Continuation Sheet USPC: 702/19,22,23,85,104,180,189;435/4,6,7,1,7,92,69,1,287,2,436/173,518,250/238,324/304,309																											
Applicant CERNO BIOSCIENCE LLC																											
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of ___ sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>				<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand 20 October 2005 (20.10.2005)		Date of completion of this report 21 February 2006 (21.02.2006)																									
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer John E Barlow Telephone No. 571 272 1750																									

Form PCT/IPEA/409 (cover sheet) (April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/34618

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Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☐ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

- ☐ the international application as originally filed/furnished
- ☒ the description:
pages 1-48, 50-51, 53, 58-61 as originally filed/furnished
pages* 49, 52, 54, 55, 56, 57, 62, 63, 64, 65, 66 received by this Authority on 20 October 2005

(20.10.2005)

pages* 1-7 received by this Authority on 20 October 2005 (20.10.2005)

- ☒ the claims:
pages 50-51, 53, 58-61 as originally filed/furnished
pages* 49, 52, 54-57, 62-66
pages* 49, 52, 54-57, 62-66 received by this Authority on 20 October 2005 (20.10.2005)
pages* 49, 52, 54-57, 62-66 received by this Authority on 20 October 2005 (20.10.2005)

- ☒ the drawings:
pages 1-22 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/figs NONE
- ☐ the sequence listing (specify): NONE
- ☐ any table(s) related to the sequence listing (specify): NONE

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to the sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Form PCT/ISA/409 (Box No. I) (April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. **FILE COPY**
PCT/US04/34618**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Inventive Step (IS)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Industrial Applicability (IA)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Continuation of IPC:

G06F 19/00(2006.01), 15/00(2006.01), G01N 21/00(2006.01), 21/01(2005.01), C12Q 1/00(2006.01)

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 1-113.

The opinion as to Novelty was negative (No) with respect to claims NONE.

The opinion as to Inventive Step was positive (Yes) with respect to claims 1-113.

The opinion as to Inventive Step was negative (NO) with respect to claims NONE.

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-113.

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE.

Claims 1-27 meet the criteria set out in PCT Article 33(2)-(3), because the prior does not teach or fairly suggest ions and its isotopes, a convolution between calculated isotope abundances and specified target peak shape function, let alone the subsequent deconvolution. The fact that the peak width changes with wavenumber (Col 8 line 15) renders a convolution invalid. Further, Axelsson does not deal with calibration ion and its exact molecular composition (Col 3 lines 25-38) but rather a model (average) compound assumed to share a general mass distribution of a molecule whose precise composition is unknown (Col 3 lines 30 and Col 4 line 63-Col 5 line 8), does not teach using the actual peak shape function but the estimated one (Col 3 lines 40), does not teach a convolution between true isotope distribution and specified target peak shape function, let alone the subsequent deconvolution to form a filter.

Claims 28-52 meet the criteria set out in PCT Article 33(2)-(3), because the prior does not teach or fairly suggest perform peak analysis to arrive at peak areas or peak positions and does not use weighted regression. Axelsson does not perform weighted regression and does not report integrated peak areas.

Claims 53-90 meet the criteria set out in PCT Article 33(2)-(3), because the prior does not teach or fairly suggest obtaining, from a given calibration ion with its isotopes, at least one actual mass spectral peak shape function, specifying mass spectral target peak shape functions within respective mass spectral ranges, and performing a deconvolution operation between the obtained at least one mass spectral peak shape function and the mass spectral target peak shape functions to obtain at least one calibration filter from a result of the deconvolution operation.

Claims 91-100 meet the criteria set out in PCT Article 33(2)-(3), because the prior does not teach or fairly suggest peak width normalization but rather allows it be variable as is (Col 8 line 15), let alone integrating the mathematical inverse of the function to obtain a transform function. Neither Wang nor Gehrke deals with ions in mass spectroscopy. Further, Gehrke does not teach peak width normalization, let alone integrating the mathematical inverse of the function to obtain a transform function.

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Supplemental Box

Claims 101-104 meet the criteria set out in PCT Article 33(2)-(3), because the prior does not teach or fairly suggest the issue of external vs internal calibration. Fig. 3 of Wang et al. has no parts pointing to internal calibration or infusion or online/offline mixing. Col 8 line 11 does not mention adding calibration standard into a test sample, let alone continuous infusion or online mixing.

Claims 105-113 meet the criteria set out in PCT Article 33(2)-(3), because the prior does not teach or fairly suggest calibration by selecting at least one peak in the data to act as a standard; deriving a calibration filter based on the at least one selected peak; using the calibration filter to analyze other peak in the data.